

Amendments to the Claims

This listing of claims will replace all prior versions, and listings of claims in the application.

Listing of Claims:

1. (Previously presented) An anti-reflux valve prosthesis to be placed in an esophagus, the prosthesis comprising:
an annular fixation body;
a plurality of retractable spikes spaced along a circumference of the annular body adjacent one end thereof to secure the prosthesis in the esophagus;
a one-way valve depending from the annular fixation body, the one way valve configured to allow orthograde passage therethrough and to inhibit retrograde passage of gastric contents; and
a gas permeable membrane to allow retrograde permeation of a gas therethrough.
2. (Original) The anti-reflux valve prosthesis of claim 1 wherein the prosthesis is configured to be perorally installed.
3. (Original) The anti-reflux valve prosthesis of claim 2 wherein the prosthesis is configured to be perorally removable.
4. (Original) The anti-reflux valve prosthesis of claim 1 wherein the gas permeable membrane is substantially liquid impermeable.
5. (Original) The anti-reflux valve prosthesis of claim 1 wherein the one-way valve is a sleeve valve.
6. (Original) The anti-reflux valve prosthesis of claim 1 wherein the prosthesis is comprised of a biologically inert material.
7. (Original) The anti-reflux valve prosthesis of claim 6 wherein the prosthesis is comprised of a fluorinated polymer.
8. (Cancelled)
9. (Original) The anti-reflux valve prosthesis of claim 8 wherein the esophagus is cancer free.
10. (Cancelled)
11. (Cancelled)

12. (Cancelled)
13. (Currently amended) An anti-reflux valve prosthesis for peroral implantation in an esophagus, the prosthesis comprising:
an annular body;
a valve depending from the annular body, said valve allowing orthograde passage therethrough and inhibiting retrograde passage of gastric contents; [[and]]
a plurality of spikes spaced along a circumference of the annular body adjacent one end thereof, wherein each the of the spikes include a tip at a free end thereof and a base attached to the annular body and are selectively retractable between a deployed and a retracted alignment with respect to the circumference; and
a dog formed between the base and the tip of each of the spikes.
14. (Original) The anti-reflux valve prosthesis of claim 13 wherein said valve is a sleeve valve.
15. (Original) The anti-reflux valve prosthesis of claim 14 wherein said sleeve valve comprises a plurality of magnets, the magnets secured at a distal end thereof to facilitate closure of the sleeve valve.
16. (Original) The anti-reflux valve prosthesis of claim 13 further comprising a gas permeable membrane to allow retrograde permeation of gas therethrough.
17. (Original) The anti-reflux valve prosthesis of claim 16 wherein the gas permeable membrane is substantially liquid impermeable.
18. (Cancelled)
19. (Cancelled)
20. (Currently amended) The anti-reflux valve prosthesis of claim 13[[19]] wherein a plurality of keepers are positioned on an exterior surface of the annular body for receiving the dogs and locking the spikes in the deployed alignment.
21. (Currently amended) The anti-reflux valve prosthesis of claim 13[[18]] wherein each of the spikes is outwardly bendable at the base between the retracted alignment and the deployed alignment.
22. (Original) The anti-reflux valve prosthesis of claim 21 wherein said retracted alignment is generally longitudinal.

23. (Original) The anti-reflux valve prosthesis of claim 21 wherein said deployed alignment is generally radially outward.
24. (Cancelled)
25. (Cancelled)
26. (Original) The anti-reflux valve prosthesis of claim 14 wherein the annular body is internally threaded.
27. (Previously presented) The anti-reflux valve prosthesis of claim 13 wherein the valve is implanted to relieve symptoms of a patient with Gastroesophageal reflux disease.
28. (Original) The anti-reflux valve prosthesis of claim 27 wherein the patient does not suffer from esophageal cancer.
29. (Previously presented) An implantation tool in combination with the anti-reflux valve prosthesis of claim 13, the tool comprising:
an inner tube and an outer tube, said tubes being generally concentrically aligned;
a nipple secured to a distal end of the inner tube, the nipple coupled with the annular body of the anti-reflux valve prosthesis; and
a headpiece secured to a distal end of the outer tube to engage the retractable spikes and outwardly extend them into position by advancing the headpiece into abutment with the nipple.
30. (Previously presented) The combination of claim 29 wherein the outer tube is configured to be advanced or retracted as the outer tube is rotated with respect to the inner tube.
31. (Previously presented) The combination of claim 30 further comprising a handle, said handle being secured adjacent to a proximal end of the inner tube for manipulation thereof.
32. (Previously presented) The combination of claim 31 further comprising a second handle secured adjacent to a proximal end of the outer tube to facilitate rotation of the outer tube with respect to the inner tube.
33. (Previously presented) The combination of claim 29 further comprising a fiber optic cable disposed within a central longitudinal passage of the inner tube for viewing the esophagus.

34. (Previously presented) The combination of claim 29 wherein the headpiece includes a plurality of transverse passages formed therein in communication with a transverse bore in a wall of the inner tube and a central longitudinal passage.
35. (Previously presented) The combination of claim 34 further including a vacuum source in communication with the central longitudinal passage.
36. (Cancelled)
37. (Cancelled)
38. (Previously presented) An implantation tool in combination with the anti-reflux prosthesis of claim 13, the tool comprising:
the anti-reflux valve prosthesis of claim 13;
means for mounting the anti-reflux valve prosthesis onto a headpiece of the tool;
means for positioning the anti-reflux valve prosthesis in the esophagus;
means for deploying the plurality of radial spikes with the tool;
means for pulling a vacuum across a longitudinal passage of the tool; and
means for drawing a lumen of the esophagus inwardly for facilitating impaction of the spikes.
39. (Cancelled)
40. (Cancelled)
41. (Previously presented) An implantation tool in combination with the anti-reflux valve prosthesis of claim 13, the tool comprising:
means for perorally inserting and positioning the anti-reflux valve prosthesis into the esophagus;
means for deploying the plurality of spikes, the spikes depending radially from the anti-reflux prosthesis; and
means for impaling the esophagus upon the spikes to hold the prosthesis in place.
42. (Cancelled)
43. (Cancelled)
44. (Currently amended) An implant tool in combination with the anti-reflux prosthesis of claim 13 ~~in an esophagus~~, the tool comprising:
the anti-reflux valve prosthesis of claim 13;

means for releasably engaging a nipple of the tool with the annular body of the prosthesis;

means for perorally inserting the valve prosthesis in to the esophagus near a gastroesophageal junction;

means for extending the spikes fully outward into a deployed alignment for engagement with a lumen of the esophagus;

means for uncoupling the nipple from the prosthesis; and

means for withdrawing the tool from the esophagus.

45. (Previously presented) An extraction tool in combination with the anti-reflux valve prosthesis of claim 13, wherein the prosthesis includes radial spikes extended therefrom, the tool comprising:
 - an inner tube and an outer tube, said tubes being generally concentrically aligned;
 - a nipple secured to a distal end of the inner tube, the nipple configured to be releasably coupled with the annular body; and
 - a crown secured to a distal end of the outer tube, the crown having a plurality of tangentially projecting shoes to receive and retract the extended radial spikes.
46. (Previously presented) The combination of claim 45 wherein the outer tube is configured to be advanced or retracted as the outer tube is rotated with respect to the inner tube.
47. (Previously presented) The combination of claim 46 the tool further comprising a handle, the handle being secured adjacent to a proximal end of the inner tube for manipulation thereof.
48. (Previously presented) The combination of claim 47 the tool further comprising a second handle secured adjacent to a proximal end of the outer tube to facilitate movement of the outer tube with respect to the inner tube.
49. (Previously presented) The combination of claim 45 the tool further comprising a fiber optic cable disposed within a central longitudinal passage of the inner tube for viewing the esophagus.
50. (Previously presented) The combination of claim 45 the tool further comprising an overtube having a shield of enlarged diameter at a distal end thereof, wherein the overtube is slidable over the outer tube to receive the plurality of spikes to facilitate removal of the prosthesis from the esophagus.

51. (Previously presented) The combination of claim 50 wherein the shield is tapered from a larger diameter at a distal end to a smaller diameter at a proximal end.
52. (Previously presented) The combination of claim 45 wherein the crown is configured to be removable and replaced with a headpiece, the headpiece configured to assist in reinstalling the prosthesis into the esophagus.
53. (Cancelled)
54. (Cancelled)
55. (Previously presented) An extraction tool in combination with the anti-reflux prosthesis of claim 13, the tool comprising:
 - means for perorally inserting the tool into the esophagus, wherein the tool comprises a nipple and a crown;
 - means for engaging the nipple into the annular body of the prosthesis, wherein the plurality of spikes are extended;
 - means for advancing the crown with respect to the nipple, the crown configured to retract the spikes; and
 - means for removing the tool and engaged prosthesis from the esophagus.
56. (Cancelled)
57. (Cancelled)
58. (Cancelled)
59. (Cancelled)
60. (Cancelled)
61. (Cancelled)
62. (Currently amended) A implantation tool in combination with the anti-reflux prosthesis of claim 13[[56]], the tool comprising:
 - means for bending the plurality of spikes inwardly and means for positioning a shield in a first position over the spikes;
 - means for perorally inserting the prosthesis into the esophagus near a gastroesophageal junction;
 - means for moving the shield into a second position while holding the prosthesis in place to release the spikes into the memory position;

means for rotating an inner tube of the tool with respect to the annular body of the prosthesis to uncouple a nipple of the tool from the prosthesis; and
means for withdrawing the tool from the esophagus.

63. (Cancelled)
64. (New) An anti-reflux valve prosthesis for peroral implantation in an esophagus, the prosthesis comprising:
an internally threaded annular body;
a sleeve valve depending from the annular body, said valve allowing orthograde passage therethrough and inhibiting retrograde passage of gastric contents; and
a plurality of spikes spaced along a circumference of the annular body adjacent one end thereof, wherein the spikes are selectively retractable between a deployed and a retracted alignment with respect to the circumference.
65. (New) The anti-reflux valve of claim 64 wherein each of the spikes include a tip at a free end thereof and a base attached to the annular body.
66. (New) The anti-reflux valve of claim 65 wherein a dog is formed between the base and the tip of each of the spikes.
67. (New) The anti-reflux valve of claim 66 wherein a plurality of keepers are positioned on an exterior surface of the annular body for receiving the dogs and locking the spikes in the deployed alignment.
68. (New) The anti-reflux valve of claim 64 wherein said retracted alignment is generally longitudinal.
69. (New) The anti-reflux valve of claim 64 wherein said deployed alignment is generally radially outward.
70. (New) An implantation tool in combination with the anti-reflux valve prosthesis of claim 64, the tool comprising:
an inner tube and an outer tube, said tubes being generally concentrically aligned;
a nipple secured to a distal end of the inner tube, the nipple coupled with the annular body of the anti-reflux valve prosthesis; and
a headpiece secured to a distal end of the outer tube to engage the retractable spikes and outwardly extend them into position by advancing the headpiece into abutment with the nipple.

71. (New) The combination of claim 70 wherein the outer tube is configured to be advanced or retracted as the outer tube is rotated with respect to the inner tube.
72. (New) The combination of claim 70 further comprising a fiber optic cable disposed within a central longitudinal passage of the inner tube for viewing the esophagus.
73. (New) The combination of claim 70 wherein the headpiece includes a plurality of transverse passages formed therein in communication with a transverse bore in a wall of the inner tube and a central longitudinal passage, said central longitudinal passage including a vacuum source in communication therewith.
74. (New) An implantation tool in combination with the anti-reflux prosthesis of claim 64, the tool comprising:
the anti-reflux valve prosthesis of claim 64;
means for mounting the anti-reflux valve prosthesis onto a headpiece of the tool;
means for positioning the anti-reflux valve prosthesis in the esophagus;
means for deploying the plurality of radial spikes with the tool;
means for pulling a vacuum across a longitudinal passage of the tool; and
means for drawing a lumen of the esophagus inwardly for facilitating impaction of the spikes.
75. (New) An implant tool in combination with the anti-reflux prosthesis of claim 64 in an esophagus, the tool comprising:
the anti-reflux valve prosthesis of claim 64;
means for releasably engaging a nipple of the tool with the annular body of the prosthesis;
means for perorally inserting the valve prosthesis in to the esophagus near a gastroesophageal junction;
means for extending the spikes fully outward into a deployed alignment for engagement with a lumen of the esophagus;
means for uncoupling the nipple from the prosthesis; and
means for withdrawing the tool from the esophagus.
76. (New) An extraction tool in combination with the anti-reflux valve prosthesis of claim 64, wherein the prosthesis includes radial spikes extended therefrom, the tool comprising: an inner tube and an outer tube, said tubes being generally concentrically aligned;

a nipple secured to a distal end of the inner tube, the nipple configured to be releasably coupled with the annular body; and

a crown secured to a distal end of the outer tube, the crown having a plurality of tangentially projecting shoes to receive and retract the extended radial spikes.

77. (New) The combination of claim 76 wherein the outer tube is configured to be advanced or retracted as the outer tube is rotated with respect to the inner tube.
78. (New) The combination of claim 77 the tool further comprising a handle, the handle being secured adjacent to a proximal end of the inner tube for manipulation thereof.
79. (New) The combination of claim 78 the tool further comprising a second handle secured adjacent to a proximal end of the outer tube to facilitate movement of the outer tube with respect to the inner tube.
80. (New) The combination of claim 76 the tool further comprising a fiber optic cable disposed within a central longitudinal passage of the inner tube for viewing the esophagus.
81. (New) The combination of claim 76 the tool further comprising an overtube having a shield of enlarged diameter at a distal end thereof, wherein the overtube is slidable over the outer tube to receive the plurality of spikes to facilitate removal of the prosthesis from the esophagus.
82. (New) The combination of claim 81 wherein the shield is tapered from a larger diameter at a distal end to a smaller diameter at a proximal end.
83. (New) The combination of claim 76 wherein the crown is configured to be removable and replaced with a headpiece, the headpiece configured to assist in reinstalling the prosthesis into the esophagus.
84. (New) An extraction tool in combination with the anti-reflux prosthesis of claim 64, the tool comprising:
 - means for perorally inserting the tool into the esophagus, wherein the tool comprises a nipple and a crown;
 - means for engaging the nipple into the annular body of the prosthesis, wherein the plurality of spikes are extended;
 - means for advancing the crown with respect to the nipple, the crown configured to retract the spikes; and

means for removing the tool and engaged prosthesis from the esophagus.

85. (New) An extraction tool in combination with the anti-reflux valve prosthesis of claim 64 wherein the annular body is internally threaded and spikes are attached to a proximal end of the annular body, comprising:
- inner and outer concentric tubes;
 - a nipple secured to a distal end of the inner tube for threadably coupling the annular body;
 - a handle secured adjacent to a proximal end of the inner tube for manipulation thereof;
 - wherein the inner tube and the outer tube are in threaded interengagement for advancement of the outer tube by rotating the outer tube with respect to the inner tube;
 - a crown secured to a distal end of the outer tube and having a plurality of tangentially projecting shoes disposed on a distal end of respective longitudinal arms spaced along a circumference of the crown in correspondence with the spikes for bending the fixation spikes inwardly;
 - an overtube having a shield of enlarged diameter at a distal end thereof, wherein the overtube is slidable over the outer tube to receive the plurality of inwardly bent spikes within the shield to inhibit laceration of the esophagus during movement of the prosthesis.